

wherein if X contains from 19 to 22 carbon atoms, Z cannot be hydrogen if Y is amide.

REMARKS

No claims have been cancelled or added. Claim 12 has been amended. As acknowledged in the present Office Action, claims 1-22 are pending in this application.

THE 35 U.S.C. SECTION 102(b) REJECTION OF CLAIMS 12, 14 AND 16-17 OVER NELSON ('827):

Claims 1, 3, 5-6, 10, 12, 14 and 16-17 were rejected under 35 U.S.C. section 102(b) as allegedly being anticipated by U.S. Patent No. 4,497,827 to Nelson et al. Applicants' claims 12-20 and 22 are directed to a chemical compound having a recited structure.

- **The Nelson reference does not anticipate each and every element of claims 12, 14 and 16-17.**

"It is axiomatic that for prior art to anticipate under §102 it has to meet every element of the claimed invention." Stoller v. Ford Motor Co., 18 USPQ2d 1545, 1547 (Fed. Cir. 1991). The Nelson reference only appears to anticipate Applicants' claim 12 when: X contains from 19 to 22 carbon atoms; Z is hydrogen; and Y is amide. Claim 12 has been amended to exclude the above overlap so that the Nelson reference does not anticipate each and every feature of amended claim 12. Amended claim 12, and claims depending therefrom, are patentable for at least this reason.

THE 35 U.S.C. SECTION 102(b) REJECTION OF CLAIMS 1, 3, 5-6 AND 10 OVER NELSON:

Claims 1, 3, 5-6, 10, 12, 14 and 16-17 were rejected under 35 U.S.C. section 102(b) as allegedly being anticipated by U.S. Patent No. 4,497,827 to Nelson et al. Applicants' claims 1-11 and 21 are directed to specified methods including, *inter alia*,

the use of a chemical compound having a recited structure to inhibit transport of anandamide in an individual or animal or to modify the rate of anandamide inactivation in an individual or animal.

- **The Office Action admits that the features of claims 1, 3, 5-6 and 10 are not explicitly anticipated by the Nelson reference.**

When the PTO asserts that there is an explicit or implicit teaching or suggestion in the prior art, it must indicate where such a teaching or suggestion appears in the reference. In re Yates, 211 USPQ 1149, 1151 (CCPA 1981). The Office Action has not indicated where the Nelson reference teaches that administration of Applicants' recited compounds would inhibit anandamide transport.

The Office Action only asserts that "[I]t is inherent that said administration of arachidonamide would inhibit anandamide transport." Thus, the Office Action admits that there is no explicit teaching or suggestion of Applicants' claimed invention in the Nelson reference and that the rejection of claims 1, 3, 5-6 and 10 is based only on an allegedly inherent property.

- **The burden is on the Examiner to provide a basis in fact and/or technical reasoning to establish with certainty that an asserted property is inherently present in the prior art.**

The express, implicit, and inherent disclosures of a prior art reference may be relied upon in the rejection of claims under 35 U.S.C. §§102 or 103. See MPEP §2112. However, "[t]he doctrine of inherency is available only when the prior inherent event can be established as a certainty. That an event may result from a given set of circumstances is not sufficient to establish anticipation. Probabilities are not sufficient . . . A prior inherent event cannot be established based upon speculation or where a doubt exists." Ethyl Molded Products Co. v. Betts Package Inc., 9 USPQ2d 1001, 1032-1033 (E.D. Ky. 1988). The Court of Appeals for the Federal Circuit has reinforced this position stating: "[t]he fact that a certain result or characteristic may

occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic." In re Rijckaert, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993). To rely on the theory of inherency in rejecting a claim under 35 U.S.C. §§102 or 103, ". . . the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied art." Ex parte Levy, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original). "Anticipation of inventions set forth in product claims cannot be predicated on mere conjecture respecting the characteristics of products that might result from the practice of processes disclosed in the references." Phillips Petroleum Co. v. U.S. Steel Corp., 6 USPQ2d 1065, 1076-1077 n12 (D. Del. 1987), *aff'd* 9 US PQ2d 1461 (Fed. Cir. 1989).

Further, the chemical arts are known to be unpredictable so that a person of ordinary skill is cautious about extrapolating from teachings within those arts. See, for example, In re Marzocchi, 169 USPQ 367, 368-370 (CCPA 1971), acknowledging the unpredictability within the chemical arts. This caution in extrapolating from chemical teachings is especially true when, as in the present case, the Nelson reference teaches a biochemical mechanism that is different from the mechanism disclosed in the pending application. In such a case, a person of ordinary skill in the art understands that the teachings are uncertain and the different mechanisms may not be related.

- **The Examiner has not met the required legal burden to establish with certainty that the Nelson reference inherently anticipates Applicants' claim s 1, 3, 5-6 and 10.**

The MPEP and relevant legal precedent both mandate that to rely on the theory of inherency in rejecting a claim under 35 U.S.C. §§102 or 103, ". . . the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied art." This is especially true when the allegedly inherent characteristic is in the unpredictable field of biochemistry as is the present application.

The Office Action attempts to discharge this heavy legal burden in only 5 lines, starting at page 2, point 1, second paragraph therein. The entirety of this text recites:

Nelson discloses a pharmaceutical composition comprising arachidonamide. Nelson teaches a method of administering the composition to humans. See abstract, column 1 line 17-column 2 line 25, column 3 line 67-column 4 line 14, column 12 lines 17-50. It is inherent that said administration of arachidonamide would inhibit anandamide transport.

The first two lines merely discuss the fact that the Nelson reference discloses a pharmaceutical composition and a method of administering that composition to humans. The cited text of Nelson, at most, supports the first two lines.

Thus, the total extent of the basis in fact and/or technical reasoning legally required to reasonably support the determination that Applicants' claimed invention necessarily flows from the teachings of Nelson is the single, unsupported, sentence "[I]t is inherent that said administration of arachidonamide would inhibit anandamide transport." In fact, the present Office Action is devoid of ANY fact or ANY technical reasoning as to why Applicants' claims 1, 3, 5-6 and 10 necessarily flow from teachings within the Nelson reference. Clearly, an unsupported assertion in a single sentence is legally insufficient to support the rejection of Applicants' claims 1, 3, 5-6 and 10. Applicants respectfully traverse this rejection and respectfully assert that the Examiner should withdraw this rejection or provide the legally required basis in fact and/or technical reasoning to reasonably support this rejection. Applicants' claims 1, 3, 5-6 and 10, and claims dependent therefrom, are patentable for at least this reason.

THE OBVIOUSNESS DOUBLE PATENTING REJECTION OVER MAKRIYANNIS ('459):

Claim 1 was rejected under the judicially created doctrine of obviousness type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,874,459.

In this rejection the Office Action admits that the conflicting claims are not identical, but asserts that they are not patentably distinct from each other "because both the patent and instant application are administering to a human or animal the same compounds in a method for inhibiting anandamide transport.

The present application is directed to recited compounds that inhibit transport of anandamide across cell membranes. The transport inhibitor does not activate the cannabinoid receptors or inhibit anandamide hydrolysis *per se* but instead targets activity of the anandamide transporter. See page 4, lines 2-8 of the present application.

The '459 patent is directed to a method of using recited compounds to inhibit anandamide amidase. The inhibition of anandamide amidase results in increased levels of anandamide in the individual. Increased levels of anandamide result in increased stimulation of the cannabinoid receptors. See column 3, lines 38-43 of the '459 patent. The Office Action does not indicate where the '459 patent teaches or suggests inhibiting activity of the anandamide transport mechanism in an individual or animal. In fact, a computer search of the '459 patent does not reveal one instance of the word "transport" therein.

Since the '459 patent and present application are drawn to distinct inventions, Applicants respectfully traverse double patenting rejection and assert that it should be withdrawn.

THE OBJECTION TO CLAIMS 2, 4, 7-9, 11, 13, 15 AND 18-22:

Claims 2, 4, 7-9, 11, 13, 15 and 18-22 were objected to as being dependent upon a rejected base claim, but were indicated to be allowable if rewritten in independent form including all of the limitations of the base, and any intervening, claims. Applicants respectfully assert that independent claims 1, 10 and 12 are either correctly patentable or in condition to overcome their respective rejection. Accordingly, claims 2, 4, 7-9, 11, 13, 15 and 18-22 are no longer dependent from a rejected base claim and are therefore patentable.

In sum, all of the present objections and rejections have been fully considered. The pending claims are novel and non-obvious in view of the cited references. Accordingly, it is believed that the application now stands in condition for allowance and prompt, favorable action thereon as earnestly solicited.

Respectfully submitted,

Alexandros MAKRIYANNIS et al

By 

James E. Piotrowski
Registration No. 43,860
Alix, Yale & Ristas, LLP
Attorney for Applicant

Date: May 9, 2002
750 Main Street
Hartford, CT 06103-2721
(860) 527-9211

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